DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 16, 2016

Arrow International, Inc.
c/o Mr. William Paquin
Quality Assurance/Regulatory Affairs Manager
9 Plymouth Street
Everett, MA 02149

Re: K021462
Trade/Device Name: Arrow Intra-Aortic Balloon (IAB) Catheter with a Fiber Optic Sensor and a Measurement System
Regulation Number: 21 CFR 870.3535
Regulation Name: Intra-aortic balloon and control system
Regulatory Class: Class II
Product Code: DSP
Dated: May 1, 2002
Received: May 7, 2002

Dear William Paquin:

This letter corrects our substantially equivalent letter of June 6, 2002.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric E. Richardson -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K021462

Device Name
Arrow Intra-Aortic Balloon (IAB) Catheter With A Fiber Optic Sensor And A Measurement System

Indications for Use *(Describe)*
The Arrow Intra-Aortic Balloon (IAB) Catheter With a Fiber Optic Sensor and a Measurement System is clinically indicated for the following conditions:
a. Acute Coronary Syndrome
b. Cardiac and Non-Cardiac Surgery
c. Complications of Heart Failure

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Teleflex®

Arrow International, Inc
9 Plymouth Street
Everett, MA 02149
USA
Phone: 617-389-6400
Fax: 617-387-2157
www.teleflex.com

510(k) Summary K021462

Arrow Intra-Aortic Balloon (IAB) Catheter with a Fiber Optic Sensor and a Measurement System

Date Summary Updated: July 28, 2015

A. Submitter's Name:

Arrow International, Inc.
9 Plymouth Street,
Everett, MA 02149

Updated Correspondent Address:

Fusun Tufan
Senior Regulatory Affairs Manager
Arrow International, Inc.
16 Elizabeth Drive,
Chelmsford, MA 01824
Phone (978)250-5100
Fax (978)250-5105

B. Company Contact

Michael Malis
Director RA/QA
Arrow International, Inc.
16 Elizabeth Drive,
Chelmsford, MA 01824
Phone (978)250-5100
Fax (978)250-5105

C. Device Name

Trade Name:	Arrow Intra-Aortic Balloon (IAB) Catheter with A Fiber Optic Sensor and A Measurement System
Common Name:	Intra-Aortic Balloon (IAB) with a Fiber Optic Sensor and Measurement System
Classification Name:	Balloon, Intra-Aortic and Control System

D. Predicate Devices

The following table contains the predicate devices which Arrow claims substantial equivalence.

Table 1: Predicate Devices

510(k)	Intra-Aortic Balloon Description
K000729	IAB 8Fr, 30cc Arrow Ultra 8
K000729	IAB 8Fr, 40cc Arrow Ultra 8
K963920	IAB 8Fr, 30cc Arrow NarrowFlex Universal
K993966	IAB 8Fr, 40cc Arrow NarrowFlex Universal
K981660	IAB 8Fr, 40cc RediGuard Arrow ArmorGlide

The fiber optic sensor and measurement system is technologically equivalent to the following device:

1. Camino Ventrix Subdural Tunneling Pressure Monitoring Kit from Camino NeuroCare, 5955 Pacific Center Blvd., San Diego, California 92121, Premarket Notification K982702.

E. Description of Device

IAB's are designed to provide cardiac assist therapy. In cardiac assist therapy a standard electronic pressure transducer can be connected externally to the central lumen of an IAB as a means of monitoring arterial pressure.

The purpose of the IAB device modification is to provide an alternative means for obtaining arterial pressure readings directly from the tip of an IAB catheter, as opposed to a standard electronic pressure transducer that is connected externally to the central lumen of an IAB.

A pressure sensor is attached to a flexible optical fiber in the IAB catheter. The sensor is positioned within the tip of the IAB catheter and the fiber runs the length of the inner lumen, exiting at the trifurcation and attaches to an optical connector. The sensor in the IAB catheter optically transmits light to a sensor measurement system. The sensor measurement system displays and outputs an arterial pressure.

Because the fiber optic sensor is positioned directly in the aorta, an arterial pressure can be directly obtained as opposed to obtaining arterial pressure readings through the end of a fluid-filled column and transducer. Additionally the fiber optic signal is optical not electrical, therefore, the pressure signal is immune to any electrical noise/interference that can affect a standard electronic pressure transducer. The fiber optic measurement system outputs the pressure via a digital or analog signal. The output signal can be input into a patient monitoring system or Intra-Aortic Balloon Pump (IABP).

F. Indications for Use

The Arrow Intra-Aortic Balloon (IAB) Catheter with a Fiber Optic Sensor and a Measurement System is clinically indicated for the following conditions:

a. Acute Coronary Syndrome
b. Cardiac and Non-Cardiac Surgery
c. Complications of Heart Failure

G. Technological Characteristics

The device has similar technological characteristics as previously cleared pressure sensors.

The results of the laboratory tests demonstrate that the device is substantially equivalent.